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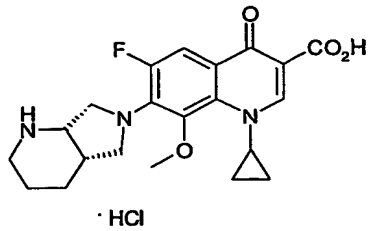
(54) Title: POLYMORPHS OF 1-CYCLOPROPYL-7-([S,S]-2,8-DIAZADICYCLO[4.3.0]NON-8-YL)-6-FLUORO-1,4-DIHYDRO-8-METHOXY-4-OXO-3-QUINOLINE CARBOXYLIC ACID HYDROCHLORIDE AND METHODS FOR THE PREPARATION THEREOF



(I)

(57) Abstract: Two novel crystalline forms, designated form A and form B of the antibacterial agent 1-cyclopropyl-7-([S,S])-2,8-diazadicyclo[4.3.0]non-8-yl)-6-fluoro-1,4-dihydro-8-methoxy-4-oxo-3-quinoline carboxylic acid hydrochloride of formula (I), the preparation thereof, and their pharmaceutical compositions are described. These crystalline forms, which are characterized by greater stability and ease of preparation and of formulation, can be produced by industrially applicable methods which comprises the steps of: a) suspending 1-cyclopropyl-7-([S,S])-2,8-diazadicyclo-[4.3.0]non-8-yl)-6-fluoro-1,4-dihydro-8-methoxy-4-oxo-3-quinoline carboxylic acid hydrochloride in a solvent selected from an alcohol and a polyalcohol, b) heating the mixture under reflux, c) cooling, d) isolating the product which is separated, (form A) and additionally, e) reslurrying the solid at reflux in a solvent selected from alcohols and polyols or mixtures thereof, in which the resulting mixture has an overall water content of between 2.5% and 0.01% by weight, f) isolating the product (form B).

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